



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,987	06/23/2000	Richard E. Fulton	3663-5	9195
22442	7590	11/05/2003		
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202			EXAMINER ANDERSON, CATHARINE L	
			ART UNIT 3761	PAPER NUMBER 25
DATE MAILED: 11/05/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,987

Applicant(s)

FULTON, RICHARD E. *on*

Examiner

C. Lynne Anderson

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-30, 41, 42 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 41, 42 and 56-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 42 disclose an intermittent mechanical motion of the catheter that is caused by the deliver of said lytic agent. It is unclear how the deliver of the lytic agent causes the intermittent mechanical motion of the catheter. The instant specification disclose in the last paragraph of page 12 that the pulse wave forces of the pump as it delivers the lytic agent cause the intermittent mechanical motion of the catheter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3761

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 20-30 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Monetti et al. (6,030,397).

With respect to claims 20, 26, and 56, Monetti discloses a pharmomechanical device, as shown in figure 1, comprising a catheter 30 having a corkscrew configuration along its length, as shown in figure 2 and described in column 9, lines 35-36. The device is intended to increase the surface area of a clot while not causing damage to the vascular structure, as disclosed in column 3, lines 8-32. The catheter rotates between 30 rpm and 600 rpm, as disclosed in column 9, line 4. The device comprises a means 50 for rotating the catheter 30. The use of a lytic agent is disclosed in column 9, line 6.

With respect to claims 21-23, the device is fully capable of running for a prolonged period of time; if the motor is turned on for 5, 10, or 24 hours, the device will run for that amount of time.

Art Unit: 3761

With respect to claims 24-25 and 29-30, the applicant has not provided any additional structure to cause the mechanical means to have intermittent operation, and it is therefore the examiner's position that the motor is capable of being turned on and off for a prolonged period of time, for equal amounts of time, and such that the ratio of inactivation time to activation time is greater than 1 or greater than 50.

With respect to claim 27, the device is designed to extend for a substantial length of the vessel, as disclosed in column 3, lines 14-16.

With respect to claim 28, the lytic agent is released through the drive shaft 30, which may therefore be considered an occluding element as it maintains the concentration of the lytic agent in the portion of the patient's blood vessel where the drive shaft 30 ends.

Claims 20-27, 29-30, and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al. (5,882,329).

With respect to claims 20, 26, and 56, Patterson discloses a pharmomechanical device, as shown in figure 3, comprising a catheter 12 having a corkscrew configuration along its length, as shown in figure 5 and described in column 13, lines 37-39. The device is fully capable of being used to increase the surface area of a clot while not causing damage to the vascular structure. The catheter rotates between 30 rpm and 600 rpm, as disclosed in column 17, line 18. The device comprises a means 22 for rotating the catheter 12.

Art Unit: 3761

With respect to claims 21-23, the device is fully capable of running for a prolonged period of time; if the motor is turned on for 5, 10, or 24 hours, the device will run for that amount of time.

With respect to claims 24-25 and 29-30, the applicant has not provided any additional structure to cause the mechanical means to have intermittent operation, and it is therefore the examiner's position that the motor is capable of being turned on and off for a prolonged period of time, for equal amounts of time, and such that the ratio of inactivation time to activation time is greater than 1 or greater than 50.

With respect to claim 27, the device is designed to extend for a substantial length of the vessel.

With respect to claims 57 and 58, the catheter rotates at 30 rpm, as disclosed in column 17, line 18.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (703) 306-5716. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Application/Control Number: 09/599,987

Page 6

Art Unit: 3761

CWA

cla

October 28, 2003



WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700